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Combined Primary Subintimal and Endoluminal Angioplasty for Ischaemic Inferior-limb Ulcers in Diabetic Patients: 5-year Practice in a Multidisciplinary 'Diabetic-Foot' Service

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Abstract *Introduction:* This study aims to assess the patency, the clinical success and the limb-salvage rates of combined subintimal (SA) coupled to endoluminal angioplasty (EA) as the initial treatment of ischaemic inferior-limb ulcers in diabetic patients and to study the influence of other concurrent factors in the tissue-healing process.
Materials and method: Since September 2002 until December 2007, a consecutive series of 176 limbs with manifold ischaemic wounds in 161 diabetic patients were treated by associated multilevel angioplasties in a multidisciplinary 'diabetic-foot team' (a third-line diabetic-care institution integrating two departmental hospitals). There were 98 associated SA with EA procedures, 26 re-vascularisations by single SA technique and 52 others including selective multilevel EAs that were retrospectively reviewed. The mean follow-up period was 22.1 months (in the range of 1–50 months) by clinical and duplex evaluation (every 6 months).

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Results: The initial technical success was noted in 149 limbs (84%). For the single or associated SA procedures, 102 of 124 procedures were successful (82%) and 145 of 150 of the miscellaneous EAs (96%) evinced an equally favourable outcome. The 27 initially failed endovascular procedures (22 SA and five EA) required 16 surgical re-vascularisation, eight adjuvant endovascular procedures besides three amputations. A total of 21 secondary and five tertiary angioplasties were equally necessary during the entire follow-up period of these patients. The 30-day survival rate was 99% (one patient died from myocardial infarction). In a intention-to-treat analysis, the cumulative primary and secondary patencies at 12, 24, 36 and 48 months were 62%, 45%, 41% and 38%, together with 80%, 69%, 66% and 66%, respectively. The aggregate clinical success rates at the same intervals were 86%, 77%, 70% and 69%, while the corresponding limb-salvage proportions showed 89%, 83%, 80% and 80%, respectively. The primary patency was negatively affected at 1 and 4 years by the length of the occluded segment (>10 cm) and the end-stage renal disease (ESRD) ($p < 0.0001$). The limb-salvage rates were unfavourably influenced at the same periods by the extent of tissue defects (>3 cm), the ESRD and the presence of osteomyelitis. In addition, at 4 years, the age (>70 years), the accompanying peripheral neuropathy, the bedridden status and the presence of cardiac failure (left ventricular ejection fraction (LVEF) < 30%) appeared equally as negative predictors ($p < 0.0001$) for wound healing and limb rescue.

Conclusion: Primary angioplasty represents a low aggressive and efficacious method to improve the healing process in diabetic ischaemic ulcers. However, beyond appropriate re-vascularisation, even repetitive if necessary, achieving satisfactory limb-salvage rates probably implies a multidisciplinary control of the presenting risk factors for wound healing as well.

Primary angioplasty in the treatment of chronic inferior limb (TASC A and B lesions), has been showed to compare with both prosthetic and venous bypass surgery.[1] With regards to the critical-limb ischaemia (CLI) and the more severe TASC C and D arterial lesions,[1] observational[2–4] or recent randomised studies[5] indicate equivalent short- to medium-term results for the two therapeutic options.

For this category of frail (fragile) patients world over, the features of the disease/morbidity — involving extended inflammation and tissue loss — make them somewhat reluctant to undergo re-vascularisation.[6,7] However, increasing contemporary reports are to date proposing primary angioplasty as feasible procedure in most diabetic subjects with optimal clinical results.[1,4,8,9]

The purpose of this study was twofold: first, to assess the technical and clinical outcome of combined subintimal (SA) and endoluminal angioplasty (EA) as the primary therapeutic strategy in diabetic patients with CLI ulcers in a non-academic (tertiary referral) diabetic centre. Second, we tried to consider and rank, in a multidisciplinary approach, the influence of several concurrent factors participating in the healing process of diabetic wounds, beyond the angioplasty-related re-establishment of flow.

Material and methods

Patients

Since September 2002 until December 2007, a series of 176 inferior-limb ischaemic wounds in 161 diabetic CLI patients were treated in our institution (two departmental hospitals) by primary multilevel angioplasties and were retrospectively analysed following convenient ethical approval. Fifteen patients received a staged, bilateral re-vascularisation. All patients were intended for a primary angioplasty approach, excepting the cases with extensive or irrecoverable foot gangrene (Wagner stage 5)[10] and inevitable amputation. There were 98 associations of SA with EA procedures, 26 re-vascularisations by single SA technique and 52 others involving selective multilevel EAs. Severe ischaemic ulcerations, distal necrosis and swelling (Rutherford categories 5 and 6)[11] were appointed either at the foot level (Wagner classification grade 2–4)[10] in 104 limbs (59%) or as isolated calf ulcers in 42 cases (24%). In 30 (17%) limbs, complex below-the-knee trophic lesions were noted. This series included 98 men, and the mean age was 70.9 years (in the range of 46–89 years). Patient characteristics and risk factors are summarised in Table 1. Of the diabetic population included in this study, 33% of the cases (59 of 176) were insulin dependent and 70% (124 of 176) presented different stages of peripheral neuropathy according to the UK screening test scale.[12] Over two-thirds of the patients exhibited more than 10 years of assigned diabetes.

Single SA ($n = 26$) or associated with EA ($n = 98$) was realised in an extra-luminal manner in a total of 124 limbs (70%). The presence of aneurismal disease, recent occlusions with echo-lucent material (systematic preoperative duplex evaluation) or clinical acute ischaemia was not considered for this approach. The mean length of the re-canalised segments was 8.6 cm (ranging from 3 to 28 cm). In five cases, SA was realised in limbs with previous femoro-popliteal ($n = 4$) or femoro-distal ($n = 1$) failed bypasses.

EA, as the sole technique ($n = 52$) or associated with SA ($n = 98$), was performed in a total of 150 cases of stenoses > 70% and also for short occlusions (<3 cm). In practice, a path of least resistance (endo- or extra-luminal) was attempted to re-canalise all the long and short occlusions ($n = 134$, by using SA = 124 and EA = 10), while pure stenoses ($n = 42$) were treated via a luminal approach. The

Table 1 Patients' features and risk factors

Patients characteristics/risk factors	Nr. limbs ($n = 176$)	(n%)
Age > 70 years	$n = 73$	41
Hypertension	$n = 123$	69
Smoking	$n = 90$	51
Coronary disease	$n = 122$	69
Ejection fraction < 35%	$n = 42$	23
Chronic renal insufficiency	$n = 86$	48
End-stage renal disease dialysis	$n = 33$	18
Hypercholesterolemia	$n = 101$	57
Cerebrovascular disease	$n = 40$	22
COPD	$n = 49$	27
Local features/limbs		
Two or three crural artery occluded	$n = 129$	73
Incomplete or occluded pedad pedal arch	$n = 36$	20
Length of the occlusion ≥ 10 cm	$n = 55$	31
Peripheral neuropath/the UK screening score[b]: (1–9 pts)	$n = 124$	70
Osteitis	$n = 57$	32
Wagner score[a] grades 2–5	$n = 79$	44
Bedridden	$n = 20$	11

[a] Wagner classification.
[b] UK Neuropathy screening centre.

technical features of the 98 combined EA and SA interventions are presented in Table 2. The complementary details concerning the independent SAs or EAs are displayed in Table 3.

Focussing on the segment that presented the main lesions, we graded the limbs as follows: 14 limbs (8%) with TASC type B lesions, 70 cases (40%) featuring TASC type C arterial disease (iliac, $n = 1$; femoro-popliteal, $n = 17$ and crural, $n = 52$) and 92 limbs (52%) revealing TASC type D lesions (iliac, $n = 1$; femoro-popliteal, $n = 22$ and crural, $n = 69$).[1] According to the number of patent tibial arteries persisting in the calf (scored from 0 to 3), the mean crural arterial run-off was 0.8 at the time of the procedures.

Definitions

Tabulation of the clinical information of the inferior-limb ischaemia was evaluated according to the revised criteria of SVS/ISCVS[10] and the TASC (II) recommendations.[1] The sensory neuropathy has been quantified using the Semmes–Weinstein monofilaments according to the UK peripheral neuropathy screening score[12] and the Wagner classification was employed to itemise the foot trophic lesions.[10] Patency, limb-salvage and survival rates were defined based on the recommended standard of reporting practices.[11] Technical success was noted in the absence of residual stenosis in >20%. Clinical success was recorded when there was an increase in the ankle–brachial index (ABI) of >0.10 or marked healing trends (improvement with at least two Rutherford categories with or without minor amputations).

Statistical analysis

All the results were reported in an intention-to-treat analysis. The Kaplan–Meier life-table method was used to determine the outcome of the primary and secondary patencies, the clinical success, the limb-salvage and the patient-survival rates at sequential time intervals. The initial technical success and primary patency results of our team were compared between the first- and the second-half time period of our experience (years: 2002–2004 vs. 2005–2007) using the log-rank (Mantel–Cox) and the Breslow–Wilcoxon tests. Specific parameters were analysed as categorical variables at 1 and 4 years, applying the two-

Table 2 The technical characteristics of the 98 combined endoluminal and subintimal angioplasties

Leading SA		The main procedure ($n = 98$)		Accompanying EAs						
Initiation level		Re-entry level		Iliac	Profonda fem	SFA	Popliteal	Anterior tibial (AT)	Posterior tibial (PT)	Peroneal
ILIAC	($n = 5$)	Common iliac	($n = 1$)				1			
		External iliac	($n = 3$)		1	2				
		Common femoral	($n = 1$)			1				
Femoro-popliteal	($n = 34$)	SFA	($n = 5$)	1	1			2	1	
		Proximal popliteal	(n = 12)	3	1			2	5	1
		Distal popliteal	($n = 3$)	1	1				1	
		Tibio-peroneal trunk	($n = 4$)					3	1	
		Peroneal	($n = 7$)	1	1				5	
		Post. tibial	($n = 3$)					1		2
Infra-popliteal and crural	($n = 59$)	Ant. tibial	($n = 7$)			3	1		2	1
		Pedal artery	($n = 2$)						1	1
		Post. tibial	($n = 23$)	2		14	1	3		3
		Plantar artery	($n = 8$)			2		5		1
		Peroneal	($n = 19$)			5	3	3	7	

Table 3 Specificities of the interventions requiring a single type of angioplasty

Independent SAs ($n = 26$)				Independent EAs					($n = 52$)	
Initiation level	Re-entry level		Target Lesion	Iliac	Profonda fem	SFA	Popliteal	Anterior tibial (AT)	Posterior tibial (PT)	Peroneal
Iliac ($n = 3$)	Common iliac	($n = 1$)	$n = 52$	$n = 7$	$n = 1$	$n = 8$	$n = 3$	$n = 12$	$n = 16$	$n = 5$
	External iliac	($n = 1$)		Associated EAs performed in the same setting:						
	Common femoral	($n = 1$)	*ILIAC*			1				
Femoro-popliteal ($n = 7$)	Distal popliteal	($n = 3$)	*CONTRLAT./ILIAC*	1	1	1	1		1	
	Tibio-peroneal trunk	($n = 3$)	*COMMON FEM*	1						
	Peroneal	($n = 1$)	*SFA*	1				3	5	2
	Post. tibial	($n = 1$)	*CONTRALAT./SFA*	1						
Infra-popliteal and crural ($n = 16$)	Post. tibial	($n = 5$)	*POPLITEAL*	1		1		1	3	1
	Ant. tibial	($n = 3$)	*PROFONDA FEM*			1			1	1
	Plantar artery	($n = 1$)	*Ant. tibial*				1			
	Pedal artery	($n = 1$)	*Post. tibial*	1		1		1		1
	Peroneal	($n = 3$)	*Tibio-peroneal mark*			1		3	1	
	Peroneal distal	($n = 3$)	*Peroneal*	1			1	2	2	
			Plantar arteries			1		1	2	
			Pedal			1			1	

sided Fisher's exact test. A p-value of <0.05 was considered statistically significant. All data were incorporated in the 'GraphPad In Stat' statistics software (Graph Pad Software, Inc., San Diego, CA, USA).

The SA and PTA techniques

The preoperative medication of 160 mg of aspirin daily or clopidogrel 75 mg per day started at least 72 h before the procedure was included in each case. The SA procedures (Fig. 1) were carried out using a previously standardised protocol.[13] All the patients received 5000 IU of heparin before crossing the lesion. In some difficult re-entry manipulations (mostly due to local calcifications), an angled 5-F 'vertebral' catheter (Cook, UK) or a 5-F 'PIER' catheter (Cordis, USA) was used with good results. Occasionally, the support of an 'out-back' catheter (LuMend, Inc., Redwood City, CA, USA) ensured satisfactory results in four laborious re-canalisations. It is the author's practice to inject small doses of contrast through the 5-F catheter periodically during the dissection, in order to assess the eventual uncertain recovery of the true lumen and the state of collaterals. Nitinol stents were placed above the knee ($n = 44$, 25%) only selectively after suboptimal EA (residual stenosis $>20\%$) or only if elastic recoil in the SA channel was evidenced. For the below-the-knee EAs, usually a 2.5–3-mm low-profile balloon in a monorail 0.014-inch system (Savy, Cordis Corp., USA) or in a more stiff 0.018 over the wire system (ReeKross, Clear Stream Technologies Ltd.) was employed, strengthened by a 50–60-cm 6-F introducer sheath (Cordis, USA or Cook, UK). In 14 cases, cutting balloons (Boston, Inc., USA) were needed to treat annular calcifications in the popliteal or calf vessels ($n = 12$) or for the presence of myointimal hyperplasia after previous stenting of the superficial femoral artery (SFA; $n = 2$).

All patients were prescribed aspirin (160 mg per day) after the procedure, unless intolerant or previous treatment with clopidogrel, ticlopidin or oral anticoagulation. In such cases, these latest medications were prolonged.

Other local wound treatment included debridement, disinfection and, in selected cases, linear closure or skin grafts (autografts) were applied. In this group of study, no other auxiliary methods to stress local tissue regeneration (vacuum-assisted wound closure, biosynthetic skin substitutes or hyperbaric oxygen therapy) were added after the first targeted re-vascularisation.

Follow-up

The patients were postoperatively followed up with periodical clinical and duplex scan evaluation, including the ABI quantification when feasible. This follow-up was scheduled 1 month after discharge and every 6 months thereafter. The mean follow-up was 22.3 months (in the range of 1–61 months).

Results

The aggregate initial technical success was noted in 149 limbs (84%). For the whole SA procedures, 102 of the 124 patients were successful (82%), and 145 of the 150 patients

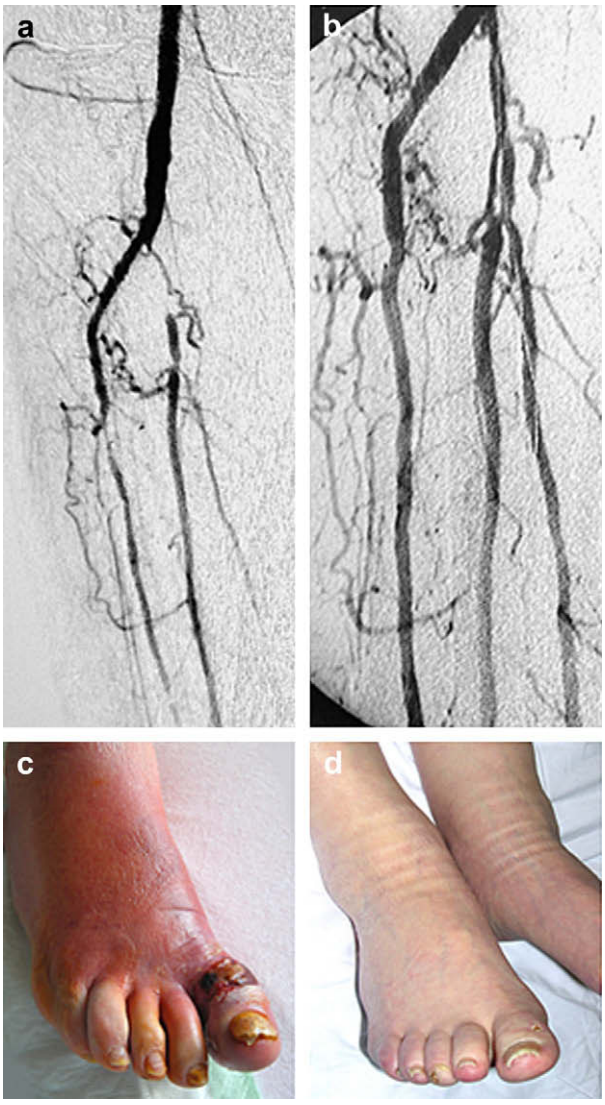

Figure 1 (a) Severe critical-limb ischaemia (CLI) atherosclerotic pattern involving all the crural arteries. (b) Combined SA and EA re-vascularisation with re-opening of the three tibial trunks. (c) Initial presentation of the foot with tissue necrosis of the right hallux (Wagner grade 3) and inflammatory swelling. (d) Clinical result at 5 months.

undergoing miscellaneous EA interventions (96%) evinced an equally favourable outcome.

In the 27 initially failed endovascular interventions (22 SA and five EAs), majority were noted following SAs, due to the lack of re-entry of the true lumen ($n = 14$). Conversely, a difficult initiation of the subintimal plane was assigned in four SAs. The other four SA inadequacies included an arterial wall perforation and a failure to seal a leak or to re-start a new extra-luminal channel ($n = 1$) and the occurrence of elastic recoil with secondary thrombosis of the subintimal channel ($n = 3$). There were five EA failures with regards to suboptimal dilatations (residual stenosis $> 20\%$) in the context of heavy crural-vessel calcifications.

Surgical re-vascularisations were mandatory in 16 instances (14 bypasses and two thrombectomies), other adjuvant endovascular procedures were performed in eight limbs (three iterative SAs, two percutaneous thrombo-aspirations and three local thrombolysis along with EA), besides three inevitable amputations.

The ABI assessment showed a mean increase of 0.34 (in the range of 0.10–0.70). The aggregate 30-day peri-operative complication rate (in an intention-to-treat analysis) was 12% (22 of the 176 cases). Major complications were noted in 10 cases (5%): four limbs exhibiting initial acute ischaemia and surgical re-vascularisation, one myocardial infarction treated by emergent coronary angioplasty, three reversible renal insufficiencies (contrast-enhanced) and two groin haematomas claiming surgical haemostasis.

Minor complications with confined clinical rebounds were registered in 12 other cases (7%): (1) three cases of distal spasms cleared by nitroglycerin-derivatives administration, (2) four cases of flow-restricted arterial perforations managed by prolonged balloon occlusion ($n = 2$) and stent placement in the SFA ($n = 2$), (3) three cases of distal embolisms controlled by percutaneous ($n = 1$) or surgical ($n = 2$) thrombectomy and (4) two superficial groin haematomas having spontaneous local resolution.

The 30-day survival rate was 99% (one case of myocardial infarction). The cumulative primary and secondary patencies at 12, 24, 36, 48 and 60 months (±SEM) were 62% (±3.8), 45% (±4), 41% (±4.4), 38% (±4.7) and 38% (±5), together with 80% (±3.1), 69% (±3.7), 66% (±4.4), 66% (±4.3) and 66% (±4.3), respectively, in a intention-to-treat analysis.

The aggregate clinical success rates at the same intervals were 86% (±2.8), 77% (±4.1), 70% (±5.6), 69% (±5.8) and 69% (±5.8), while the corresponding limb-salvage proportions showed 89% (±2.6), 83% (±3.8), 80% (±4.6), 80% (±4.8) and 80% (±4.8) in a same approach (Fig. 2).

The primary patency correlated to the initial technical success and the limb-salvage data were compared between the first- and the second-half time period of our experience (September 2002–December 2004 vs. January 2005–December 2007) using the log-rank (Mantel–Cox) and the Breslow–Wilcoxon tests (Figs. 3 and 4). While primary patency significantly improved during these two periods following an inherent learning curve of our team (Fig. 3) ($p = 0.039$, confidence interval; CI: 1.030–3.365, HR: 1.86, Chi square = 5.31), there was no statistical expression concerning the limb-salvage rates ($p = 0.64$, CI: 0.48–3.35, HR: 1.27, Chi square = 0.23) (Fig. 4). The distribution of complications and initial failures was also perhaps relevant in the concept of learning curve: while three acute ischaemias were noted in the first period instead of one in the second, there were 16 technical failures in 77 patients (20%) in the first interval vs. 11 failures in 99 patients (11%) in the second time period.

Primary patency and limb salvage were also analysed related to the presence/absence of some specific factors using the univariable twofold Fisher's exact test.

While the length (>10 cm) of the treated artery and ESRD were negative predictors at 1 and 4 years ($p < 0.0001$), the decline of the left ventricular function (ejection fraction $< 30\%$) appeared significant only at 4 years ($p < 0.0001$) for the primary patency. With regards to the limb salvage, this was unfavourably affected at both intervals by the extent of the tissue loss (ulcers > 3 cm), the presence of osteomyelitis and the co-existence of ESRD

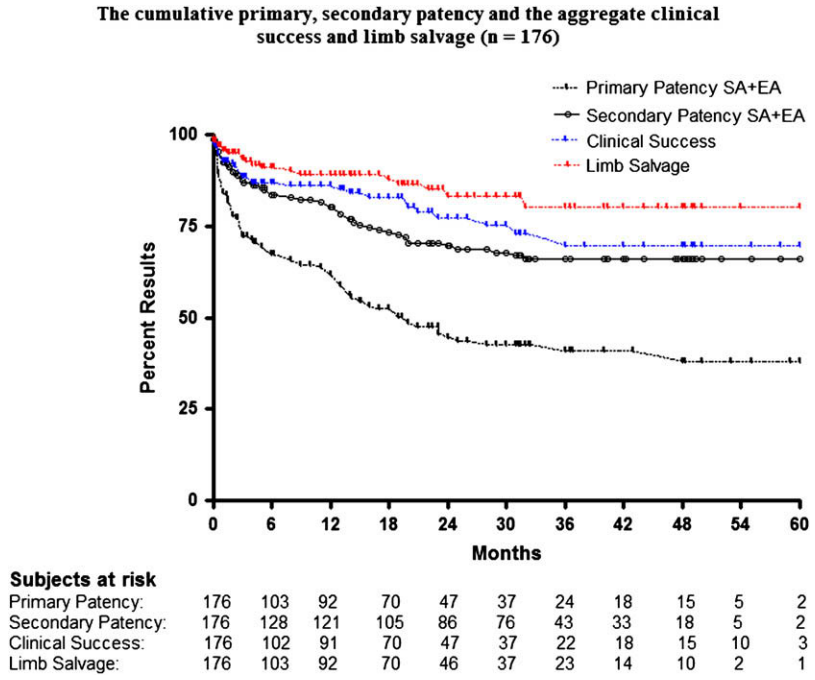

Figure 2 The cumulative primary, secondary patency, clinical success and limb-salvage rates using the Kaplan—Meier life-table method. All results were reported in an intention-to-treat analysis, including the 27 initial technical failures.

($p < 0.0001$). The same parameter showed a detrimental correlation with age (>70 years), poor ejection fraction (<30%), peripheral neuropathy and the bedridden status of patients ($p < 0.0001$) merely at 4 years.

A global stratification of the 176 treated ischaemic limbs revealed a complete healing of ulcers with or without minor amputation in 129 of the 176 limbs (73%) mainly in the 4th to the 6th month following the initial intervention. In the reminder 47 cases (including the three early amputations), despite the recovery of a correct postoperative arterial flow (duplex control), there were 40 limbs that never became ulcer-free and four additional amputations for extensive local sepsis in Wagner grade 3—4 lesions. Totally, for the 44 ulcerated limbs (25%), re-vascularisation 'alone' could not influence the local recovery process. On the other hand, within the initially 129 unimpaired healed limbs, in 40 of the 129 limbs, recurrent ulcerations appeared after a mean 'wound-free' period of 10.6 months (in the range of 3—26 months). Globally, during the entire follow-up period, a total of 23 secondary, five tertiary angioplasties, 17 bypasses and five other secondary surgical procedures were noted, mostly in the first 10 postoperative months.

Throughout the study period, there were 24 (13%) major amputations (three in the early failures, four in the group of correct angioplasty issues and 17 among the whole follow-up, following iterative re-vascularisations or wound

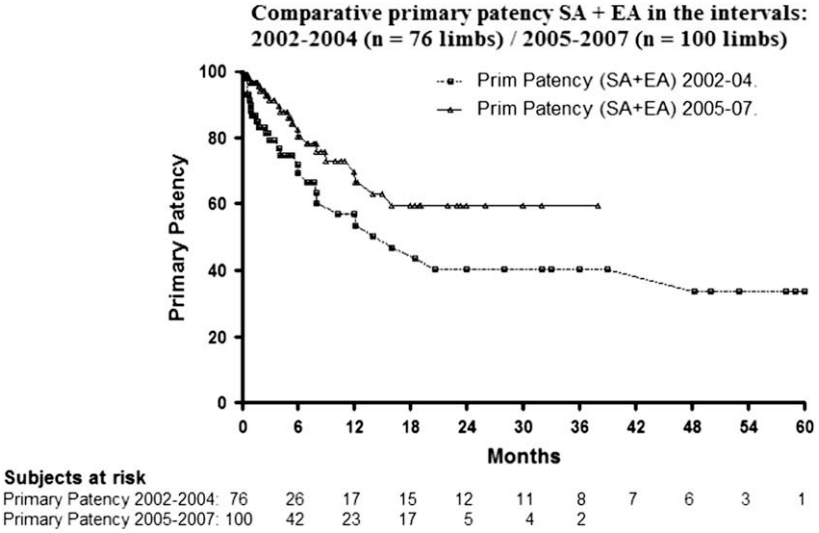

Figure 3 A comparative appraisal of the technical success and the primary patency between September 2002 and December 2004 vs. January 2005 and December 2007, using the log-rank (Mantel—Cox) and the Breslow—Wilcoxon tests.

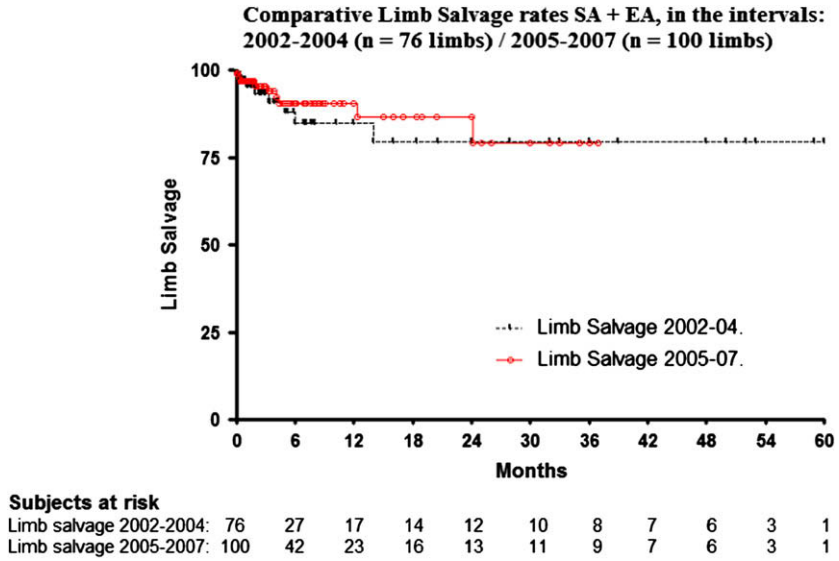

Figure 4 Similar estimation concerning the limb-salvage rates between the two half time periods of our experience, applying analogous statistical resolution.

relapses). We documented 67 (38%) minor amputations, while 36 patients died (25 of cardiac and other vascular-related causes, four of neoplasic disease, two of pulmonary sepsis, four of miscellaneous renal and digestive aetiologies and one of an unspecified cause). The cumulative survival rates (Fig. 5) were 93%, 81%, 70%, 60% and 45% at 12, 24, 36, 48 and 60 months, respectively.

Discussion

Although most of the diabetic inferior-limb ulcers appear neuropathic, in more than 40% of the cases, ischaemic participation has also been evoked.[1,10,14,15] Primary infra-inguinal angioplasty for CLI became increasingly reported as feasible, with low complications and comparable limb-salvage proportions with surgery.[1,4,5,8,16]

The SA technique has emerged a few decades ago,[13] gaining an increasing popularity in the treatment of long occluded arterial segments not only in claudicants but also in CLI.[4,9,17] A relatively high restenosis rate is probably compensated by its low invasiveness, reduced cost and hospital stay and a wide reproducibility, without interfering with further surgical options.[4,9,17] These points seem to be in line with our observations. The mid-term primary patency rates were modest, influenced by an incontestable learning curve: 39% and 37% at 2 and 3 years in the first-half of our experience and 53% and 46% at the same time intervals after 2005 (Fig. 3).

Dick et al., in line with the observations of De Rubertis et al., emphasise the reduced primary patency rates for angioplasty, particularly in the subset of diabetic CLI population.[8,18] They conclude, however, that the diabetic context should not be considered a contraindication to endovascular therapy, whose benefit may be mandatory to a close surveillance and sustained iterative procedures. In our practice, the primary angioplasty approach has become a consistent policy to treat the complex lesions encountered in the diabetic CLI limbs. Whether it concerns occlusions, targeting a substitutive endo- or extra-luminal passage in a plane of decreased resistance, or for stenoses through the native endoluminal way, an opening channel through angioplasty has been attempted. However, the relatively high percentage of initial technical failures (16%) in our series may probably correlate with two independent factors: (1) a wide inclusion criteria also including 'hostile' endovascular presentations (long diseased segments, failed bypasses or extended calcifications) and (2) the principal use of angioplasty in this series as the sole endovascular technique, probably to be included in our future experience with other alternative methods in selected cases (laser re-canalisations or rotational endarterectomy, etc.).

The endovascular patency seems to be independently hampered by specific factors such as the length of the diseased arterial segment[17] and the addition of renal insufficiency.[1,4,19,20] These observations are joining our notifications. In addition, the ESRDs have been found to be

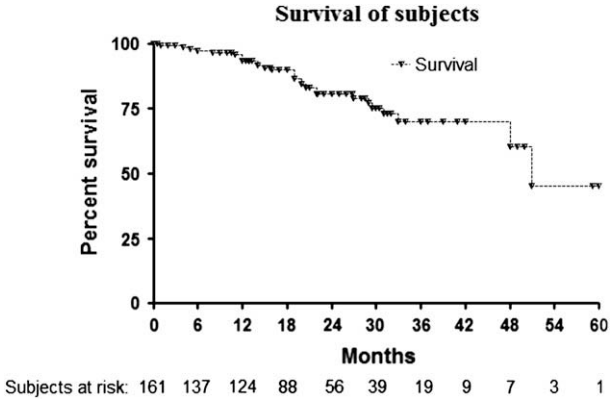

Figure 5 The survival rate of the patients during the study follow-up.

favourable for limb salvage in our group ($p < 0.0001$ at 1 and 4 years) matching with other similar clinical reports.[6,19,20] Unlike primary patency, limb salvage was less affected during the different periods of the study: 80%, 79% before 2005 and 86%, 80% after this time period, respectively (Fig. 4), owing probably to the propensity for early and iterative re-vascularisations.

Other factors detrimental to limb salvage in our group were the congestive heart failure and the impaired ambulation, having equal connotations in the series of Conrad et al. [21] and Taylor and colleagues.[22]

Owing to multidisciplinary team surveillance, a complete healing of ulcers with or without minor amputation was assigned in 129 of the 176 limbs (73%), while nine others showed consistent trends for recovery but without complete closure. These data seem to fit with the results of Bargellini et al. who observed 75% ulcer closures after primary infra-inguinal SAs, during a mean follow-up of 23 months,[20] or according to the 77% healing proportion at 1 year reported by the EURODIALE study.[23] In our experience, majority of the tissue defects were recovered between the 4th and 6th month, and these observations corroborate with other similar analysis.[15,21,23]

Neuropathy was also a relatively common characteristic in our group (63%) and was found to induce a pejorative influence on limb salvage at 4 years ($p < 0.0001$).

Some authors have suggested that successful re-vascularisation improves the arteriolar circulation in the foot substantially, but not completely, yet the diabetic neuropathic limbs still remain at risk for further ulcerations or failure to heal.[10,14,23]

In the present study, the other factors resulting in unfavourable outcome on limb salvage, with matching analogous observations in the literature, were the ulcer sizes and depth,[10,15,23] older age[23] and the presence of local sepsis.[14,15,23]

The present study has some clear limitations. First, the re-vascularisation technique reflects the experience of three interventionists, therefore their inherent learning curves, personal preferences in patient selection and technical skills could have biased the uniformity of the results. Second, the retrospective nature of the study has resulted in the relatively fewer number of cases, thus limiting a more refined statistical interpretation.

In our experience, by scoring the manifold pattern of the diabetic CLI arterial lesions in occlusions and stenotic segments, primary angioplasty plays a useful role in attempting to restore a distal flow towards the ischaemic tissue zones. Considering both the endo- and extra-luminal paths as flexible therapeutic facets, our group recommends this approach along with a multidisciplinary dialogue and surveillance of concomitant determinants threatening limb salvage.

Conclusion

Primary angioplasty represents a low-invasive and efficacious method to increase the local conditions for healing in diabetic CLI wounds. Apart the re-establishment of the haemodynamic conditions even appointed by iterative interventions, parallel factors potentially threatening tissue recovery and limb salvage need to be controlled by a meticulous follow-up and an aggressive multidisciplinary therapeutic approach.

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